

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

REED ALAN BASH,)	CASE NO. 3:05 CV 7345
)	
Plaintiff,)	JUDGE JAMES G. CARR
vs.)	
)	
ARTHREX INCORPORATED, <u>et al.</u> ,)	<u>MEMORANDUM OF OPINION</u>
)	<u>AND ORDER</u>
Defendants.)	
)	

On August 22, 2005, plaintiff pro se Reed Alan Bash filed the above-captioned complaint against defendants Arthrex Incorporated, Jeffrey A. McMath, M.D., Ohio Orthopedic & Sports Medicine Incorporated, and Findlay Surgery Center. He asserts this court's jurisdiction pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, et seq., the Biomedical Access Assurance Act (BAAA), 28 U.S.C. § 1604,¹ the Administrative Procedures Act, diversity of citizenship in accordance with 28 U.S.C. §§ 1331(a), 1332, 1337 and the United States Constitution. Mr. Bash, a resident of Findlay, Ohio, seeks declaratory judgment that the defendants' violated the

¹ Although Mr. Bash cites "28 U.S.C. § 1604" as the Biomedical Access Assurance Act, that reference is actually a citation to the Foreign Sovereign Immunities Act (FSIA). The correct citation for the BAAA is 21 U.S.C. § 1601, et seq.

FDCA. In addition, he requests \$50,000,000.00 in compensatory damages, as well as any punitive damages the court deems appropriate.

Background

Mr. Bash was diagnosed as suffering from “a spinoglenoid notch glanglion with no evidence of [a] full or partial rotator cuff tear. The long head of the bicep tendon was seen attached normally at the bicep labral complex, proving no SLAP lesion existed.” (Compl. at 4.) He does not provide any other details regarding his condition prior to the treatment at issue in this complaint.

It is apparent that Mr. Bash was scheduled for surgery on October 23, 2003, presumably to treat the “spinoglenoid notch glanglion.” On that date, Jeffrey McMath, the orthopedic surgeon employed by Ohio Orthopedic and Sports Medicine Incorporated, allegedly “created a SLAP lesion repair area where none had existed, then proceeded to use the suture anchors to repair the damage of his own making.”(Compl. at 4.) This procedure was performed without Mr. Bash’s informed consent and Findlay Surgery Center permitted Dr. McMath to use this medical device during Mr. Bash’s surgery. He claims that the Arthrex Bio Fastak Suture Anchors used in his surgery are classified as a Class II (special controls) medical device pursuant to 21 C.F.R. parts 800 through 895, which requires that “copies of all forms and informational materials be provided to subjects to obtain informed consent.” (Compl. at 4.)

As a result of this “experimental surgery, the diagnosed spinoglenoid notch glanglion was not treated. The condition still exists. Additional surgery is mandatory to repair the damage to the shoulder created by the surgeon.”(Compl. at 4.) Furthermore, the suture anchors have allegedly failed which has left a SLAP lesion inside of Mr. Bash’s shoulder.

It is Mr. Bash's position that the sole purpose of his "unnecessary surgery" was to test repair techniques for Type II SLAP Lesions on living tissue. He has reached this conclusion after reading the article, "A Biomechanical Comparison of Repair Techniques for Type II SLAP Lesions" in the March 11, 2000 issue of The American Journal of Sports Medicine. The findings contained in the article conclude that "the use of cadaveric shoulders allows for the creation of an ideal testing model, but fails to fully represent the dynamic properties of living tissue." (Compl. at 5.) Mr. Bash alleges that the defendants are in violation of federal law and have caused permanent personal injury to him. He then lists ten counts wherein the defendants have allegedly violated various provisions of the FDCA. For the reasons set forth below, this action is dismissed.

Standard of Review

Although pro se pleadings are liberally construed, Boag v. MacDougall, 454 U.S. 364, 365 (1982) (per curiam); Haines v. Kerner, 404 U.S. 519, 520 (1972), a "district court may, at any time, sua sponte dismiss a complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil procedure when the allegations of a complaint are totally implausible, attenuated, unsubstantial, frivolous, devoid of merit or no longer open to discussion." Apple v. Glenn, 183 F.3d 477, 479 (6th Cir. 1999); see Hagans v. Lavine, 415 U.S. 528, 536-37 (1974) (citing numerous Supreme Court cases for the proposition that patently frivolous claims divest the district court of jurisdiction); In re Bendectin Litigation, 857 F.2d 290, 300 (6th Cir. 1988) (recognizing that federal question jurisdiction is divested by obviously frivolous and unsubstantial claims).

Lack of Subject Matter Jurisdiction

Federal courts are always "under an independent obligation to examine their own

jurisdiction," FW/PBS, Inc. v. City of Dallas, 493 U.S. 215, 231(1990) and a federal court may not entertain an action over which it has no jurisdiction. See Insurance Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee, 456 U.S. 694, 701 (1982). Based on the facts alleged, this court lacks subject matter jurisdiction over Mr. Bash's complaint.

Under the FDCA, manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions. 21 U.S.C. § 1601. In the Bendectin Litigation case noted above, the question of whether the FDCA permitted private actions was unresolved in the Sixth Circuit. The court noted that: "Until this court or the Supreme Court holds that there is no implied private right of action under the FDCA, the opposite position cannot be deemed either frivolous or unsubstantial." Bendectin Litigation, 857 F.2d at 300. Seven years after Bendectin, however, the question was answered by the Sixth Circuit in the negative.

In Bailey v. Johnson, 48 F.3d 965 (6th Cir. 1995), the court unequivocally held that there is no private cause of action under the FDCA. Addressing the test set forth in Touch Ross & Co. v. Fredington, 442 U.S. 560, 575 (1979) rather than the former Cort v. Ash, 422 U.S. 66 (1975) test to determine whether a statute impliedly created a private right of action, the Bailey court held: "Considering the FDCA's legislative history as set out above, we are compelled to conclude that Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA." Bailey, 48 F.3d at 968. Therefore, considering Mr. Bash's status as a private actor as well as the fact that every count set forth in his complaint alleges a violation of the FDCA, the court lacks federal question jurisdiction over his complaint.

Diversity Jurisdiction

Although the matter in controversy meets the threshold for jurisdiction based on diversity of citizenship, see 28 U.S.C. §1332(a), the diversity of citizenship must be complete such that all parties on one side of the controversy are of diverse citizenship from all parties on the other side at the time the complaint is filed. Newman-Green, Inc. v. Alfonzo-Larain, 490 U.S. 826, 828-31(1989). Mr. Bash and all of the named defendants, with the exception of Arthrex Incorporated, are identified as citizens of Ohio. Thus, diversity jurisdiction does not exist.

Administrative Procedures Act (APA)

The APA instructs that any person detrimentally affected by an agency decision is entitled to judicial review of that decision. See 5 U.S.C. § 702. However, such review is not afforded in cases where (1) the statute precludes review; or (2) the action complained of has been committed to agency discretion. See 5 U.S.C. § 701(a); Friends of Crystal River v. U.S. E.P.A., 35 F.3d 1073, 1078 (6th Cir. 1994). Therefore, although the APA imposes a presumption in favor of judicial review, Block v. Community Nutrition Inst., 467 U.S. 340, 348-49 (1984), this presumption will be overcome by clear and convincing evidence that Congress intended to preclude such review. Abbott Labs. v. Gardner, 387 U.S. 136, 140 (1967). As noted above, Congress clearly precluded Mr. Bash from pursuing a private cause of action under the FDCA and he is not entitled to relief under the APA.

Supplemental Jurisdiction

With respect to any state law claims that may exist, this court cannot exercise supplemental jurisdiction. Section § 1337(a) under Title 28 of the United States Code gives the federal courts power to exercise supplemental jurisdiction over state law claims in an action when the federal

court has original jurisdiction over claims in the action and the companion state law claims in the action "form part of the same case or controversy." City of Chicago v. International Bd. of Surgeons, --U.S.--, 522 U.S. 156 (1997). Here, it is clear this court lacks federal jurisdiction over the complaint. Therefore, there is no federal question to which the court could attach his state law claims even if it were inclined to exercise supplemental jurisdiction. Mr. Bash cannot assert any other independent basis for this court's jurisdiction over his complaint.²

Accordingly, this action is dismissed. Further, the court certifies that an appeal from this decision could not be taken in good faith.³

IT IS SO ORDERED.

S/ James G. Carr
Chief Judge

² Although Mr. Bash mentions the Biomedical Access Assurance Act in his jurisdictional statement, he does not allege any violations of the act within his complaint. The same is true with regard to his "Constitutional" claims.

³ 28 U.S.C. § 1915(a)(3) provides:

An appeal may not be taken in forma pauperis if the trial court certifies in writing that it is not taken in good faith.